

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU2004/001051

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>Int. Cl. <sup>7</sup> : C12Q 1/68, C12N 15/01, A61K 39/395 CO7K14/47<br>According to International Patent Classification (IPC) or to both national classification and IPC  |  |  |
|--|--|--|
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>See electronic databases<br>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br>See electronic databases<br>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>WPIDS, CA Medline. SCN1A, polymorphism/mutation/SNP, epilepsy/disease/febrile seizure   |  |  |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>  |  |  |
| Category*  | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No.  |
| A  | Fujiwara T et al. Mutations of sodium channel $\alpha$ subunit type 1 (SCN1A) in intractable childhood epilepsies with frequent generalized tonic-clonic seizures. Brain, 2003. 126: 531-546 |  |
| A  | Nabbout R et al. Spectrum of SCN1A mutations in severe myoclonic epilepsy of infancy. Neurology, 2003 Jun 24. 60(12):1961-7.   |  |
| A  | WO 2003/008574 A1 (BIONOMICS LIMITED) 30 January 2003  |  |
| A  | WO 2002/06521 A1 (BIONOMICS LIMITED) 24 January 2002   |  |
| A  | WO 2002/50096 A1 ((BIONOMICS LIMITED) 27 June 2002   |  |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex   |  |  |
| * Special categories of cited documents:<br>"A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed<br>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<br>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone<br>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art<br>"&" document member of the same patent family |  |  |
| Date of the actual completion of the international search<br>28 September 2004   |  | Date of mailing of the international search report<br>7 OCT 2004     |
| Name and mailing address of the ISA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaaustralia.gov.au<br>Facsimile No. (02) 6285 3929   |  | Authorized officer<br>Gillian Allen<br>Telephone No : (02) 6283 2266 |

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### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims No 65 and 66  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
The scope of these claims is so unclear that no meaningful search can be performed.
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
The ISA found that the claims were directed to multiple invention.

See Supplemental Box III for details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by:  
Claims 1-16 19-27, 29-64, 67-85 in so far as they are directed to polymorphisms in SCN1A

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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### Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

#### Continuation of Box No: III

The present claims are to 72 different mutations in 18 different ion channel genes, the mutant genes and their encoded polypeptides and antibodies thereto, and to uses of these in diagnosis or therapy.

The unifying feature of the claimed inventions is a disease-associated mutation of an ion channel gene. However, ion channel disease-associated mutations are known for every one of the ion channels of the claims, ie SCN, CHRN, KCQN, and GABR.

Therefore, since the unifying feature of the different mutations is not novel, it cannot be accepted as a special technical feature that would unite the claims.

There are therefore 72 separate inventions claimed.

However, this office believes that all claimed mutations of any one of the claimed genes could be searched without undue effort, and has chose to search the claims in so far as they are directed to polymorphisms of SCN1A

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This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in<br>Search Report | Patent Family Member  |
|---|---|
| WO 2003/008574                            | CA 2454073<br>EP 1407013                                      |
| WO 2002/06521                             | AU 200172218  |
| WO 2002/50096                             | AU 200216826<br>EP 1351968<br>US 2004110706<br>JP 2004515252T |

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX